(For official Use) Ref No._____

新界東醫院聯網
NEW TERRITORIES EAST CLUSTER

Application for Conducting Clinical Trial /Research Involving Patients in NTEC

A. Types of Application
☐ Initial Application
☐ Amendment - Please specify *(circle as appropriate)*:
Change in (i) Principal Investigator / (ii) Co-I (HA Staff Only) / (iii) Department(s) Involved

B. Study Information		
i.. Project Title or Short Title (if any):		
ii. Study Protocol No.:	iii. CREC Ref. No. :	iv. NMPA Study : ☐ Yes ☐ No If **Yes**, please provide NMPA Clinical Trial Permit no. _____
v: Type of Study:	☐ Interventional Medicinal (Drug) (Phase 1 / 2 / 3 / 4 / *BABE , *please circle as appropriate*) ☐ Interventional Non-medicinal (e.g. Surgical Procedure/ Device/ Radiological/ Behavioral) ☐ Non-interventional	
vi: Sponsor:	☐ Company Sponsored Study ☐ Investigator- initiated Study ☐ Others, please specify:_____	
vii. Anticipated First Patient In Date:	(***Clinical Trial can only be started upon approval given)***	
viii. Planned Last Patient Out Date:		

*Bioavailability and Bioequivalence Study

C. Study Personnel Information			
i. Name of Principal Investigator (PI):			
ii. PI Affiliation: ☐ HA ☐ CUHK		iii. Department/Hospital:	
iv. Working Hours of HA Staff Involved in Conducting the Clinical Trial/ Research: *(attach additional sheet if necessary)*			
Name of HA staff involved *(HAHO HR Circular 5/2008 Outside Work Policy refers)* *Not applicable to University staff*	Rank	Expected number of hours spent per week in conducting the research/ trial	
		<u>During</u> working hours per week	<u>Outside</u> working hours per week

For enquiry, please contact Clinical Research Management Office (CRMO) at 3505-4284.
For PWH study, Principal Investigators(PI) should submit through CRMO Online Application Platform for processing.
For other NTEC hospitals,PI should send the completed form and the required documents(s) to General Office of respective hospitals for processing..

D. Documents Required (Please tick and attach):

☐ Clinical Research Ethics Committee Approval (Mandatory)

☐ Clinical Trial Certificate *(for drug trial only)*

☐ copies Indemnity Form *(for sponsored trial only, can be submitted separately for process)*

☐ Memo from CRMO confirming the coverage of clinical trial insurance, or Clinical Trial Insurance Certificate *(for investigator-initiated trials only)*

☐ Undertaking with Clinical Research Pharmacy (CRP) OR Valid quotation from Phase 1 Clinical Trial Centre (P1CTC) *(for drug trial in PWH only)*

Submitted by:

Signature of PI: _____ Date: _____

Contact No: _____ E-mail: _____

Contact Person (if applicable): _____

Contact No: _____ E-mail: _____

Endorsement by COS/ Director/ Head of Department(s)

(Please use separate application form if the study involve more than one department i.e. more than one COS endorsement required)

I support the research / clinical trial commitment listed above for HCE approval and consider that service delivery of my department will not be unduly affected.

Name: _____ Signature:_____

COS in _____ , _____Hospital Date:_____

(For Official Use Only)

Approved by HCE /Delegate

Remarks:_____

Signature:_____ Date:_____

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cc HRM6/ HR NTEC Oct 2021